

Application of : Judah Z. Weinberger  
Serial No. : 09/803,773  
Date Filed : March 12, 2001

E. Remarks

Reconsideration and allowance of the present application in view of the foregoing amendments and accompanying remarks are respectfully requested.

Claims 1-4, 6-13 and 22-30 were pending in this application. Claims 1, 8, 22, 25, 29 and 30 are being amended. Claims 12 and 13 are being cancelled. Claims 1-4, 6-11, and 22-30 are pending, and of those claims 1, 8, 22, 25 and 28 are independent.

In the Office Action dated January 17, 2003, the Examiner stated that the proposed drawing correction and/or the proposed substitute sheets of drawings, filed on October 16, 2002 have been approved, that a proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application, and that the correction to the drawings will not be held in abeyance. In response, applicant believes that the Fig. 1 drawing submitted on October 16, 2002 is a replacement sheet, and was intended to be the corrected drawing. In any case, applicant is resubmitting the replacement Figure 1. The only change from Figure 1 as filed is the label "PRIOR ART" being added.

In the Office Action, the Examiner stated that claims 1-4, 6-13, 22-24, 29, and 30 were rejected under 35 U.S.C. 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner stated that regarding claim 1, it is unclear from

Application of : Judah Z. Weinberger  
Serial No. : 09/803,773  
Date Filed : March 12, 2001

the language of the claim in lines 8-9 whether or not the shape of the tube segment is determined by the shape of the balloon. Furthermore, it is unclear what is the shape of the balloon. In response, applicant has amended claim 1 to clarify that the shape of the tube segment is determined by the shape of the balloon as the balloon inflates.

In the Office Action, the Examiner stated that, regarding claim 8, it is unclear from the language of the claim in lines 8-9 whether or not the shape of the tube segment is determined by the shape of the balloon. Furthermore, it is unclear what is the shape of the balloon. In response, applicant has amended claim 8 in the same manner as claim 1.

The Examiner stated that, regarding claims 12 and 13, it is indefinite whether or not the claims are accurate. Claim 12 recites that "the tube segment is adhesively attached to the balloon or catheter shaft" and claim 13 recites that "the tube segment is attached to the balloon or catheter shaft by heat sealing." It is unclear how the tube segment can be attached to the balloon or catheter and still be "longitudinally slid over" the balloon as set forth in independent claim 8. In response, applicant has cancelled these claims.

The Examiner stated that, regarding claim 22, it is unclear from the claim language what element of the balloon catheter is "slideable over the balloon catheter"; what element of the balloon catheter is "of expandable and collapsible material"; and what element of the balloon catheter "includes radioactive material." In response, applicant has amended claim 22 to more clearly state that the tube segment is the element which is slideable over the balloon catheter, and that the tube segment is

Application of :     Judah Z. Weinberger  
Serial No.       :     09/803,773  
Date Filed      :     March 12, 2001

the element that includes radioactive material.

The Examiner stated that regarding claim 29 and 30, the preamble of the claims is inconsistent with that of the corresponding independent claim 28, further stating that claim 28 recites an apparatus and claims 29 and 30 recite a tube segment. The Examiner stated that it is unclear whether claims 29 and 30 are further limiting the combination of elements that form the apparatus or merely the tube segment of the apparatus.

This rejection in the Office Action mailed June 11, 2002. The Remarks in the Amendment filed October 16, 2002 indicate that claim 29 and 30 have been amended to overcome said rejection, but said Amendment includes no formal amendment to the claims. As such, the rejection is maintained.

In response, claims 29 and 30 have been amended in the preamble to change "tube segment" to "apparatus", and claim 28 has been amended at the end to change "tube" to "tube segment".

The Examiner rejected claims 1, 2, 7, 8, 10 and 22 as being allegedly anticipated by Klein ('284). The Examiner stated that Klein teaches device for radiation treatment of an internal body organ, which device includes a balloon catheter **34** having an inflatable balloon **32** and a cylindrical, elastic radioactive tube **10** that is longitudinally slidable over the balloon catheter. The Examiner stated that the cylindrical radioactive tube includes a distal tube segment **18,42** formed of a mixture of radioactive material **30** and non-radioactive material **38**. The Examiner stated that the tube segment **18,42** formed can be an expandable and collapsible material. The Examiner stated that the tube segment is expandable in a range of sizes. The Examiner

Application of :     Judah Z. Weinberger  
Serial No.       :     09/803,773  
Date Filed      :     March 12, 2001

stated that, in operation, the balloon catheter is inserted into the body lumen; the radioactive tube is longitudinally slid over the balloon catheter such that the tube segment is disposed over the balloon; the balloon is inflated with fluid to expand the tube segment and administer a radiation dose to the luminal structure; the balloon is deflated and the tube segment collapsed; and the balloon catheter and tube are removed from the luminal structure.

The Examiner stated that claims 25-27 are rejected as being allegedly anticipated by Delfino et al. ('658). The Examiner stated that Delfino et al. teach a cylindrical stent for in vivo implantation, which stent is a tubular segment and includes a radioactive material for producing radiation. The Examiner stated that the radiation dose can be made to vary along axial and longitudinal dimensions of the tube segment by using varying concentrations of radioactive material (Fig. 7, col. 8, line 27-col. 9, line 5).

The Examiner rejected claims 2 and 9 as being allegedly obvious over Klein ('284) in view of Hess ('168). The Examiner stated that Klein teaches all of the limitations of the claims except that the radioactive material is in the form of a coating on the tube segment. The Examiner stated that it is well known in the art that a non-radioactive material can be provided with radioactive characteristics by coating the non-radioactive material with a radioactive material. The Examiner stated that Hess teaches a stent **74** which is coated with a radioactive material in order to assist in preventing restenosis of an artery. The Examiner stated that it would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment

Application of :     Judah Z. Weinberger  
Serial No.       :     09/803,773  
Date Filed      :     March 12, 2001

similar that of Klein by coating a tubular segment with a radioactive material in view of the teachings of Hess in order to produce a tube that is radioactive at its distal end.

The Examiner rejected claims 4 and 11 as being allegedly obvious over Klein ('284) in view of Lewis et al. ('552). The Examiner stated that Klein teaches all of the limitations of the claims except that the tube segment includes a non-radioactive material into which is absorbed radioactive material.

The Examiner stated that Lewis et al. teach that it is known in the art to make intra-luminal radiation devices of a non-radioactive material into which is absorbed radioactive material. The Examiner stated that it would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Klein by absorbing radioactive material into a non-radioactive material in view of the teachings of Lewis et al. in order to produce a tube that is radioactive at its distal end.

The Examiner rejected claims 6, 12, 13, 23, and 24 as being allegedly obvious over Klein ('284) in view of Fischell et al. ('282). The Examiner stated that Klein teaches all of the limitations of the claims except that the tube segment is adhesively attached to the balloon and that the balloon is inflated with a gas. The Examiner stated that Fischell et al. teach a catheter having an expandable radioactive source. The Examiner stated that the catheter includes a balloon 14 with an expandable, elastic radioactive tube segment 16 adhesively attached to the balloon 14 by an outer balloon 15 which is heat sealed (shrunk) to the inner balloon (col. 5, lines 2-6), and the balloon 14 is inflated with a carbon dioxide gas to bring the

Application of : Judah Z. Weinberger  
Serial No. : 09/803,773  
Date Filed : March 12, 2001

tube segment into proximity to a luminal structure (col. 6, lines 51-53). The Examiner stated that it would have been obvious to one having ordinary skill in the art that since the radioactive source **16** is expandable and elastic, the dosage per surface area of the source would inherently be different in an inflated state than that of the unexpanded state. The Examiner stated that it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to adhesively attach the tube segment to the balloon of a radiation treatment device similar to that of Klein in view of the teachings of Fischell et al. in order to ensure proper positioning of the expandable radioactive tube segment with respect to the balloon. The Examiner stated that it further would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a carbon dioxide gas as an inflation medium in view of the teachings of Fischell et al. in order to inflate the balloon catheter of a device similar to that of Klein as an obvious engineering design choice, merely substituting one known inflation medium for another that is capable of performing the same function.

The Examiner rejected claims 28-30 as being allegedly obvious over Delfino et al. ('658) in view of Hess ('466). The Examiner stated that Delfino et al., as discussed hereinabove, teach all of the limitations of the claims except that the apparatus further includes a balloon catheter. The Examiner stated that Hess ('466) teaches an apparatus for restenosis treatment including a balloon catheter having a shaft **72** and an inflatable balloon **78** and a stent **74**, and that it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a balloon catheter with a tubular stent similar to that of Delfino et al. in view of the teachings of

Application of : Judah Z. Weinberger  
Serial No. : 09/803,773  
Date Filed : March 12, 2001

Hess in order to deliver the stent to an area within an artery or vein for treatment.

The Examiner rejected claims 1-4, 6-13 and 22-30 under the judicially created doctrine of obviousness-type double patenting as being unpatenable over claims 1-22 of U.S. Patent No. 6,200,256 B1. The Examiner stated that although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than those of the patent.

The Examiner stated that regarding independent claims 1 and 8 of the instant application, all of the elements of the claims are recited in claims 11 and 19 of the patent. The Examiner stated that all of the aforementioned claims recite a tube segment including a radioactive material that is carried by a balloon catheter including an inflatable balloon, where the tube segment is disposed over the balloon and is made of an expandable and collapsible material such that the shape of the tube segment is determined by the shape of the balloon. The Examiner stated that claim 11 of the patent does not expressly state that the tube segment is longitudinally slid over the balloon. The Examiner stated that the method of using the apparatus, recited in claim 19 of the patent, indicates that the balloon catheter is inserted into a body lumen and a tube is inserted into the body lumen such that the tube segment is located over the balloon in two separate steps, and that it would have been obvious to one having ordinary skill in the art at the time the instant invention was made that the tube segment of the patent would have to be longitudinally slid over the balloon catheter in order to position the tube segment over the balloon after inserting the balloon catheter and the tube into a body lumen in separate steps as required by the

Application of : Judah Z. Weinberger  
Serial No. : 09/803,773  
Date Filed : March 12, 2001

method of claim 19 of the patent.

The Examiner stated that claims 2. and 9 of the instant application correspond to claim 8 of the patent, claims 3 and 10 of the instant application correspond to claim 9 of the patent, claims 4 and 11 of the instant application correspond to claim 10 of the patent, claim 12 of the instant application corresponds to claim 13 of the patent, claim 6 of the instant application corresponds to claim 12 of the patent, claim 7 of the instant application corresponds to claim 14 of the patent and that claims 13 of the instant application corresponds to claim 6 of the patent.

The Examiner stated that regarding independent claim 22 of the instant application, all of the elements of the claim are recited in claims 19 and 22 of the patent. The Examiner stated that all of the aforementioned claims recite a method for treating a disease process in the vicinity of a luminal structure having similar method steps, and that claim 22 of the patent differs from the claim of the instant application in that only a portion of the tube segment is provided with radioactive material.

The Examiner stated that claim 23 of the instant application corresponds to claim 20 of the patent and that claims 24 of the instant application correspond to claim 21 of the patent.

The Examiner stated that regarding claims 25-30 of the instant application, all of the elements of the claims are recited in claim 1 of the patent. The Examiner stated that all of the aforementioned claims recite a tube segment that is carried by a balloon catheter having a shaft and an inflatable balloon, where



Application of : Judah Z. Weinberger  
Serial No. : 09/803,773  
Date Filed : March 12, 2001

the tube segment includes a radioactive material for administering a radiation dose which varies along a dimension of the tube segment. The Examiner stated that Claim 1 of the patent limits the dimension to an axial or longitudinal dimension as the tube of that claim is only radioactive at a distal end thereof.

The Examiner stated that since the more specific patented claims "anticipate" the broader claims of the instant application, the claims are not patentably distinct.

In response to the rejection of independent of claims 1, 8, and 22, without conceding the correctness of the Examiner's position, but solely to advance prosecution, applicant has amended claim 1. Support for this amendment may be found in Figs. 3 and 4 which show the sleeve entirely encircling and covering the balloon.

In contrast, the cylindrical elastic radioactive tube 10 in Klein '284 has longitudinal slits, so that when the balloon is inflated, the balloon regions below the slits are exposed and not covered, with the exposed regions growing as the balloon expands. Accordingly, claims 1, 8 and 22 distinguish patentably over Klein '284. Claims 1, 8 and 22 have also been amended to recite that the outersurface of the tube segment is exposed, as shown in and supported by Figs. 3 and 4. This feature distinguishes patentably over any proposed combination of Klein '284 and Fischell '282.

In response to the rejection of independent claims 25 and 28 over Delfino et al. U.S. Patent No. 6,129,658, without conceding the correctness of the Examiner's position, but solely to advance prosecution, applicant has amended claims 25 and 28 to recite that the tube segment has substantially equal wall thickness

Application of : Judah Z. Weinberger  
Serial No. : 09/803,773  
Date Filed : March 12, 2001

along its longitudinal length. Support for this amendment may be found on page 14, lines 4-7. The Delfino reference in its figure 7 shows that wall thickness varies along its length, and fails to teach or suggest substantially equal wall thickness while varying the radiation dose along at least one dimension of the tube. Accordingly, claims 25 and 28 as amended are believed to be patentable over this reference.

In response to the obviousness-type double patenting rejection, without conceding the correctness of the Examiner's position, but solely to advance prosecution, applicant submits herewith as Exhibit A a Terminal Disclaimer in view of applicant's prior U.S. Patent No. 6,200,256. Applicant believes that the Terminal Disclaimer overcomes the obviousness-type double patenting rejection.

In view of the foregoing, applicants respectfully request withdrawal of the rejections of the pending claims and request allowance.

If a telephone interview would be of assistance in advancing prosecution of the subject application, the undersigned attorney invites the Examiner to telephone him at the telephone number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. If any fee is required, authorization is hereby given

Application of : Judah Z. Weinberger  
Serial No. : 09/803,773  
Date Filed : March 12, 2001


to charge the amount of any such fee to Deposit Account Number  
03-3125.

Respectfully submitted,

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correspondence is being deposited this  
date with the U.S. Postal Service with  
sufficient postage as first class mail  
in an envelope addressed to:

Assistant Commissioner of Patents,  
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 4/7/03  
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